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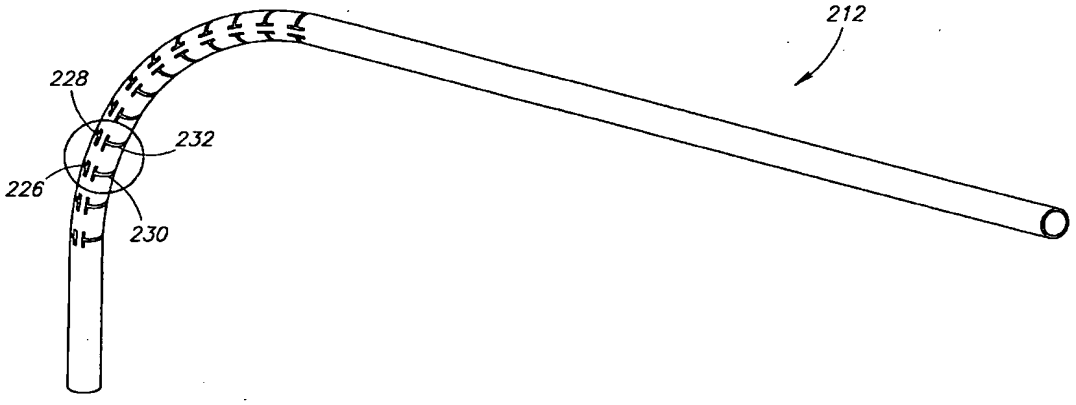
(54) Title: CANNULA



(57) Abstract: A bone cement cannula, the cannula comprising: a tube including a section adapted for plastic deformation; and a lumen in the tube capable of resisting forces of a viscous material propelled therethough at a pressure of at least 100 atmospheres.

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CANNULA

RELATED APPLICATIONS

This application claims the benefit under 119(e) of a US provisional application titled "Cannula", filed on January 26, 2006, and having serial number 60/763,003, the disclosure of which is incorporated herein by reference.

This application also claims the benefit under 119(e) of a US provisional application titled "Tools and methods for treating bones", filed on September 28, 2005, and having serial number 60/721,094, the disclosure of which is incorporated herein by reference.

This application also claims the benefit under 119(e) to U.S. application 60/762,789 entitled "Methods, Materials and Apparatus for Treating Bone and other Tissue" filed January 26, 2006, with the same inventors as this application, the disclosure of which is incorporated herein by reference.

This application also claims priority from U.S. Application 11/360,251 entitled "Methods, Materials, and Apparatus for Treating Bone and Other Tissue" filed on February 22, 2006 the disclosure of which is incorporated herein by reference.

This application is related to PCT Applications Nos. PCT/IL00/00056, filed January 27, 2000, published as WO 00/44321; PCT/IL00/00058, filed January 27, 2000, published as WO 00/44319; PCT/IL2004/000527, filed June 17, 2004, published as WO 04110300; PCT/IL2005/000812, filed July 31, 2005; the disclosures of all of which are incorporated herein by reference.

FIELD OF INVENTION

The present invention relates to devices and methods for delivery of material into an organ, for example cannulae for delivery of bone cement during an orthopedic procedure.

BACKGROUND OF THE INVENTION

Surgical and/or interventional treatment of fractured bones, osteoporotic bones, deformed bones and the like occasionally includes the use of various types of bone fillers, in order to reinforce and stabilize the bone, restore its original configuration and alleviate pain.

Vertebral fractures, for example, may be treated using the vertebroplasty technique, during which bone cement (e.g. PMMA) is injected into the vertebral body through a cannula with a diameter of approximately 1 to 4 mm. Current vertebroplasty procedures typically rely upon a needle and stylet assembly, such as a Jamshidi needle.

The currently available needle and stylet are typically made of a rigid inflexible material, *e.g.*, metal. A typical procedure includes approaching the bone, under fluoroscopy, with a needle and cannula assembly, followed by removal of the stylet. The remaining cannula serves

as a channel through which the bone cement is delivered into the bone from a reservoir connected to the cannula. Most commonly employed bone cements are not X-ray transparent.

US patent application 2004/0054377 by Foster teaches a flexible cannula made from a single continuous piece of tubing. The proximal end of the cannula is made flexible by removing material from the wall of the cannula, preferably in a spiral pattern. The disclosure of this application is fully incorporated herein by reference. Foster's cannula has a grasping device at the distal end and is designed and constructed for removal of objects from soft tissue. Foster contemplates neither delivery of cement via the cannula nor use of the cannula in orthopedic procedures.

US 6,719,761 to Reiley teaches use of steering wires to deflect (curve) a distal end of a cannula for injecting bone cement, apparently low viscosity cement is used. The disclosure of this patent is fully incorporated herein by reference.

US 6875219 to Arramon teaches a cannula with a deformable distal tip. Deformation is achieved by inserting the cannula over a curved guide. The disclosure of this patent is fully incorporated herein by reference.

US patent application publication number 2004/0260303 to Carrison, the disclosure of which is incorporated herein by reference, describes a pivoting cannula attachment to a reservoir, with the pivot adjacent a connector to the reservoir.

SUMMARY OF THE INVENTION

An aspect of some embodiments of the invention relates to a plastically deformable bone cement cannula. Optionally, plastic deformation of the cannula by hand permits a desired positioning of a cement reservoir attached thereto, relative to the cannula, imaging equipment and/or the patient. Optionally, a rigid stylet prevents plastic deformation of the cannula during insertion. Such stylet is optionally provided as a straight stylet or as a curved stylet. In an exemplary embodiment of the invention, the deformation uses less than 2Kg force. Optionally, the deformation does not damage tissues inside the body as the cannula is deformed.

In an exemplary embodiment of the invention, insertion in a straight line is provided by the cannula in an un-deformed configuration, which may be easier, and then the cannula is distorted to a form suitable for another use, for example, during injection and/or imaging.

In an exemplary embodiment of the invention, the cannula is stiff enough so that it maintains its deformation during injection of material therethrough. Optionally, the injected material is viscous, for example, viscous bone cement, injected at a high pressure, for example, at least 50 Atmospheres, at least 100 Atmospheres, at least 150 Atmospheres, at least 200 Atmospheres and/or intermediate or smaller numbers. In an exemplary embodiment of the

invention, the viscosities used are between 100 and 3000 Pascal-second,, for example 300-2000, for example, between 500 and 1000. Intermediate values may be used as well. In an exemplary embodiment of the invention, the cannula includes a series of joints which facilitate plastic deformation in a desired manner. In an exemplary embodiment of the invention, the joints are provided as joint areas including patterns of cuts and/or other weakening in the cannula body material. Optionally, the cuts are discrete. Optionally, the cuts are through cuts. Alternatively, at least some of the cuts are notches or other thinning of the cannula material. Optionally, another weakening type is provided, for example, by chemical treatment and/or mechanical and/or heat treatment.

In an exemplary embodiment of the invention, the cuts and/or weakening are designed to designate particular parts of the cannula to act as plastically deformed segments, at which a significant portion of the overall deformation is provided.

In an exemplary embodiment of the invention, the cuts and/or weakening are designed to facilitate a particular direction and/or degree of deformation or range of degrees. Optionally, the cuts are designed to reduce spacings in the cannula body, for example, spacings between lips of cuts.

Optionally such design includes one or more of cut shape, cut size, number of cuts, depth, radial profile, number of groups of cuts, relative size of cuts in different groups and/or relative position of cuts in different groups.

In an exemplary embodiment of the invention, cut/weakening design and/or distribution takes into account expected applied forces.

In an exemplary embodiment of the invention, at least some of the cuts tend to at least partially close during deformation. Optionally, the tendency to partially close is related to a degree of bending the cut is subjected to. Optionally, partial closing reduces leaking of a material injected through the cannula. Optionally, the cuts are covered to reduce leaking of a material injected through the cannula. In an exemplary embodiment of the invention, a covering which substantially reduces leaking through the slits at a pressure of 100 to 200 or 300 atmospheres is provided. The covering may be, for example, internal or external, for example, of Teflon. Optionally, a more viscous cement is used with the cannula, to reduce leakage. In an exemplary embodiment of the invention, a cement is selected which reduces leakage in other means, for example, the cement may include a liquid phase and a solid phase, with the solid particles being of the order of the narrow dimensions of the slits or larger. Optionally, leakages is reduced once the solid particles are at least 10%, at least 35%, at least

60%, at least 80% or larger of such narrow dimensions, for example, being at least 0.01 mm, 0.05 mm, 0.1 mm, 0.3 mm, or intermediate or greater in size.

In an exemplary embodiment of the invention, the joints each comprises an asymmetric cut design, in which a greater spacing between lips is provided on one side of the cut, so that bending in the direction of that side, tends to reduce the spacing.

In an exemplary embodiment of the invention, the joints are arranged in a line parallel to the cannula axis.

In an exemplary embodiment of the invention, a manufacturing process imparts flexibility to a workpiece by incising a series of cuts therein. Optionally, the process is carried out by an automated machine including control circuitry. Incision of cuts may be, for example, by one or more of lasers, chemical etching, water jets and rotating abrasive discs.

In an exemplary embodiment of the invention, the joints (e.g., cuts and/or weakening) are designed to support deformation outside a body or adjacent to a point of entry of the cannula into the body (e.g., at a proximal end thereof).

In an exemplary embodiment of the invention, each joint permits a deformation of 5, optionally 10, optionally 15 degrees or lesser or greater or intermediate values. Optionally, a total deformation of 45, optionally 90, optionally 135, optionally 180 degrees or smaller, intermediate values or greater is achieved and/or is designated as a design set point where there is minimal leakage. The length of cannula subject to deformation may vary with the total deformation implemented and/or the number of slits employed, for example, being 20 mm, 30 mm, 40 mm, or greater, smaller or intermediate in size. In an exemplary embodiment of the invention, 13 cuts provide a total deformation of 130 degrees. Greater or smaller numbers of cuts/deformation regions may be provided, for example, 7, 10, 15 or smaller, intermediate or greater numbers.

Optionally, the degree of supported deformation of a deforming segment is selected to reduce leakage and/or straightening behavior. Optionally, leakage is reduced by increasing the number of joints to the point where the product of the joint by the leakage through the joint is minimized. In general, for a desired bending angle, as the number of joints increases, the leakage is typically reduced.

In an exemplary embodiment of the invention, the cannula includes a plastically deformable tube. Optionally, the tube is a flexible tube which contains internal and/or external supports to counteract change after deformation. Optionally, the supports are designed for a particular degree and/or direction of plastic deformation.

An aspect of some embodiments of the invention relates to a bone cement cannula with at least two fill ports. Optionally, the fill ports are deployed at different angles with respect to the main cannula axis. In an exemplary embodiment of the invention, a single port is used for injection of cement. Optionally, the other port is used for guiding of a stylet or other guide tool through the cannula.

In an exemplary embodiment of the invention, unused ports are covered, plugged and/or removed from a cement flow path by a stopcock.

An aspect of some embodiments of the invention relates to a stylet, at least part of the stylet being flexible, so that angled insertion of the stylet into the patient's body is facilitated. In an exemplary embodiment of the invention, the stylet and/or a cannula is introduced into a bone, for example a vertebra. In yet another exemplary embodiment of the invention, the device is introduced into the body during laparoscopic surgery. Optionally, the stylet and/or cannula comprise a handle at their proximal end. Optionally, said handles are made of a polymer. Optionally, said handles interlock with each other. In an exemplary embodiment of the invention, the interlocking arranges the parts in a correct orientation. Optionally, the interlocking prevents inadvertent rotation or axial motion of one part relative to the other.

An aspect of some embodiments of the invention relates to a device, intended to serve as a channel for the delivery of material and/or devices/instruments into the body. In an exemplary embodiment of the invention, bone void filler, such as PMMA, is delivered via the device into a bone, for example a vertebral body. In one embodiment of the invention, the device comprises at least a cannula. Optionally, the device comprises a cannula and stylet, and may be used for accessing the target organ as well. In an exemplary embodiment of the invention, the cannula and stylet are assembled and interlocked. Optionally, cannula and stylet are interlocked at proximal handles thereof.

In an exemplary embodiment of the invention, the device is constructed from biocompatible materials. Optionally, the device is constructed from metal, such as stainless steel or a nickel-titanium alloy such as NiTinol. Optionally, at least a portion of device is formed form a polymer.

In an exemplary embodiment of the invention, the deformable cannula is designed to withstand the loads acting on it during usage, for example torque during insertion into a bone and/or removal therefrom.

Optionally, a proximal end of the cannula includes a connection means for attaching to a delivery device, for example a Luer-lock type connector.

Optionally, the cannula comprises at least one marker, for instance to indicate insertion depth and/or facilitated cannula bending direction. Such marking may be, for example, visible to human eye and/or under imaging, such as x-ray imaging.

In an exemplary embodiment of the invention, the cannula tapers at its distal end and/or is otherwise shaped, for example, to serve as a trocar.

An aspect of some embodiments of the invention relates to a cement provision cannula with an axial hole suitable for a stylet and through which cement leakage is reduced or absent. Optionally, the size of the hole reduces leakage. Alternatively or additionally, the properties of the cement used reduce leakage, for example, viscosity and/or grain size. Alternatively or additionally, the cannula and/or delivery system include a plug which selectively closes the axial hole once the stylet is removed.

There is also provided in accordance with an exemplary embodiment of the invention, a bone cement cannula, the cannula comprising:

(a) a tube including a section adapted for plastic deformation;

(b) a lumen in the tube capable of resisting forces of a viscous material propelled therethough at a pressure of at least 100 atmospheres.

Optionally, said section adapted for plastic deformation comprises a series of separate joints formed in an outer wall of the cannula. Optionally, at least one of said joints is formed by at least one cut. Optionally, at least one of said cuts is configured to close as the cannula deforms.

In an exemplary embodiment of the invention, at least one of said joints is formed by non-penetrating weakening of the cannula wall.

In an exemplary embodiment of the invention, said joints facilitate a desired deformation configuration of the cannula.

In an exemplary embodiment of the invention, said joints are sealed.

In an exemplary embodiment of the invention, the cannula comprises an outer sealing layer.

In an exemplary embodiment of the invention, the cannula comprises an inner sealing layer.

In an exemplary embodiment of the invention, said section is adapted to remain outside of a body.

There is also provided in accordance with an exemplary embodiment of the invention, a cannula, comprising:

(a) a tube including a section adapted for plastic deformation;

(b) a lumen in the tube, said lumen at least partially filled with a bone filling material.

In an exemplary embodiment of the invention, said section adapted for plastic deformation comprises a deformable sleeve.

In an exemplary embodiment of the invention, said section adapted for plastic deformation comprises a flexible tube and a configuration support for said tube.

There is also provided in accordance with an exemplary embodiment of the invention, a bone cement cannula, the cannula comprising:

(a) a tube including a tube lumen providing a channel of fluid communication between at least one injection aperture and a connector body; and

(b) at least two inlet ports defined in said tube.

Optionally, one of said ports is axially oriented.

Optionally, at least one of said ports is trans-axially oriented.

In an exemplary embodiment of the invention, the cannula comprises a port path selector adapted to selectively allow flow from one of said ports.

In an exemplary embodiment of the invention, the cannula comprises a port path blocker adapted to selectively allow block back-flow out of one of said ports.

There is also provided in accordance with an exemplary embodiment of the invention, a manufacturing process for a surgical tool, the method comprising:

(a) determining a pattern of cuts which will impart a desired deformability to a work piece;

(b) imparting the desired plastic deformability to the work piece by incising the pattern of cuts therein to produce a surgical tool; and

(c) forming said work piece into a cannula suitable for bone cement injection.

There is also provided in accordance with an exemplary embodiment of the invention, a method of delivering cement, comprising:

(a) providing a cannula with an axial guide-wire exiting through an axial hole thereof and said cannula including a side exit port;

(b) inserting said cannula into a bone;

(c) removing said stylet; and

(d) injecting cement through said cannula such that less than 20% of the cement exits through the axial hole.

There is also provided in accordance with an exemplary embodiment of the invention, a method of injecting a viscous material into a patient, comprising:

(a) inserting a cannula into a patient;

(b) bending said cannula over a length of at least 20 mm; and

(c) injecting a viscous material through said cannula.

BRIEF DESCRIPTION OF DRAWINGS

In the Figures, identical structures, elements or parts that appear in more than one Figure are generally labeled with the same numeral in all the Figures in which they appear. Dimensions of components and features shown in the Figures are chosen for convenience and clarity of presentation and are not necessarily shown to scale. The Figures are listed below.

Fig. 1 is a flow diagram illustrating a cement provision method, in accordance with an exemplary embodiment of the invention;

Fig. 2 is a front view of a deformable cement cannula with stylet inserted, in accordance with some exemplary embodiments of the present invention;

Fig. 3A is a perspective view of a deformable cement cannula prior to deformation in accordance with some exemplary embodiments of the present invention;

Fig. 3B (inset) is magnification of a portion of the exemplary cannula showing slits according to the embodiment illustrated in Fig. 3A;

Fig. 4A and 4B illustrate the cannula depicted in Figs. 3A and 3B after deformation, in accordance with an exemplary embodiment of the invention;

Fig. 4C is a diagrammatic representation of slits according to Figs 3B and 4B illustrating exemplary geometric considerations;

Fig. 5 is a plan view of the cannula of Fig. 3A;

Fig. 6 illustrates a deformed cannula including a sleeve according to an exemplary embodiment of the invention;

Fig. 7 is a perspective view of a deformable cement cannula prior to deformation in accordance with some exemplary embodiments of the present invention illustrating a lateral ejection port and a penetrating distal tip;

Fig. 8A is a perspective view of a deformable cement cannula including external support prior to deformation in accordance with an exemplary embodiment of the invention;

Fig. 8B is a perspective view of the cannula of Fig. 8A, after deformation in accordance with an exemplary embodiment of the invention;

Figs. 9A and 9B are side cross-sectional views of a plastically deformable cannula according to exemplary embodiments of the invention before and after plastic deformation respectively;

Figs. 10A and 10B are side cross-sectional views of a cannula with multiple fill ports according to exemplary embodiments of the invention without and with a port cover respectively;

Figs. 10C and 10D are side cross-sectional views of a cannula with multiple fill ports according to exemplary embodiments of the invention with a port closure valve open and closed respectively;

Figs. 10E and 10F are side cross-sectional views of a cannula with multiple fill ports according to exemplary embodiments of the invention with a stopcock directed towards an axial and a radial port respectively;

Fig. 11 is a flow diagram illustrating a method of manufacture according to exemplary embodiments of the invention; and

Fig. 12 is a schematic side cross-sectional view of a sealed-tip cannula, with an axial aperture for a stylet, in accordance with an exemplary embodiment of the invention.

DETAILED DESCRIPTION OF EXEMPLARY EMBODIMENTS

Overview of method

Fig. 1 is a flow diagram illustrating a method 100 of cement provision, in accordance with an exemplary embodiment of the invention. At 102, a cannula is inserted, optionally with or without the aid of a stylet. Such stylet may be, for example, rigid or flexible, straight or bent. Optionally, insertion 102 is monitored 104 via a medical imaging apparatus such as, for example, a fluoroscope or conventional X-ray camera. If the optional stylet has been employed, it may be removed 106 at this stage.

At 108, plastic deformation of the cannula is performed (it is noted that the cannula can be deformed before insertion), for example to be curved. At 110 a bone cement reservoir and/or delivery system are attached to a proximal end of the cannula. The order in which 108 and 110 are performed is optionally reversed. In some cases, the reservoir is integral with the cannula.

An injection 112 of cement or other viscous material is then performed.

Plastic deformation 108 and attachment 110 are optionally performed in consideration of subsequent injection monitoring 114. Because the bone cement and/or injection reservoir may not be X-ray transparent, deformation 108 is performed so that an attached cement reservoir will be outside of a relevant portion of a field of view of an X-ray image taken during injection 112. X-rays are often obtained from a directional perpendicular to the body, e.g., along the axis of the unbent cannula, but this is not always the case and the cannula deformation may be changed.

Injection 112 may be undertaken using a suitable injection device connected to the cement reservoir. In an exemplary embodiment of the invention, a high viscosity bone cement is employed and a high pressure injection device is employed, for example as described in U.S.

Application 11/360,251, the disclosure of which is incorporated herein by reference. Alternatively, a syringe or other delivery system is used. The delivered material may be, for example, PMMA or calcium-based material (such as calcium phosphate or calcium sulfate).

Optionally, a vibrator is attached to the cannula, for example, at a connector of the reservoir thereto, to facilitate flow of cement therethrough.

Optional injection 112 is monitored via a medical imaging apparatus such as, for example, a fluoroscope or conventional X-ray camera. Such monitoring may be, for example, periodically or throughout the injection 114.

When injection 112 is complete as indicated by monitoring 114, the cement reservoir is disconnected 116 and the cannula is removed 118. The order in which 116 and 118 are performed is optionally reversed.

Plastic deformation

A cannula according to exemplary embodiments of the invention is plastically deformable, as opposed to flexible. "Plastic deformation" as used herein refers to a change in shape which requires an input energy to implement, and another energy input, for example, of similar order, to reverse. In an exemplary embodiment of the invention, the input energy required for plastic deformation is sufficiently small that it can be applied manually, optionally with one hand. Optionally, once deformed, the cannula will not un-deform under forces applied to it by injecting cement therethrough and/or without external forces.

In an exemplary embodiment of the invention, the deformation is facilitated to be in a certain direction and/or one plane. Optionally, once the cannula is deformed, a weight of a cement reservoir attached thereto will tend to preserve the deformation and/or assist in resisting forces applied by injection of cement therethrough.

In an exemplary embodiment of the invention, the deformation is limited in extent and/or degree. Optionally, a desired maximum angle of deformation is facilitated by the construction and/or design of the cannula. While application of excessive force may cause additional bending beyond this maximum angle, such additional bending would be beyond the scope of designed deformation. Such additional bending may cause kinking of the cannula and/or leakage therefrom. In an exemplary embodiment of the invention, a weight of a cement reservoir attached to the cannula does not provide excessive force sufficient to deform and/or over-deform the cannula. Optionally, the reservoir provides sufficient force to deform the cannula until the reservoir rests against the patient and/or other support.

The degree of plastic deformability may be governed to some extent by materials employed in construction of the cannula. Some materials have a higher degree of plasticity

than others. Some materials have an elastic memory which causes them to tend to return to their original shape when a deforming force is removed. In exemplary embodiments of the invention, such as described below, deformation is facilitated by the geometry/structure of the cannula and/or supports provided thereto.

Slit cannula

Fig. 2 is a front view of an assembled Cannula/stylet apparatus 200 according to an exemplary embodiment of the invention, showing a partial cross-section view of handles thereof. In an exemplary embodiment of the invention, the handle orientation is matched to the slit orientation (described below), so that in typical use, the forces applied by a doctor to insert the cannula will not be in the same direction as forces that are used to bend the cannula. Optionally, the handle direction is used to indicate the desired deformation direction.

Cannula 212 includes a series of slits 224 designed to impart a desired plastic deformation capability to a specific portion of the cannula. Cannula 212 optionally includes a handle 222 at its proximal end.

Stylet 214 is inserted through cannula 212 via an inner lumen of the cannula. A cutting tip 218 of stylet 214 optionally protrudes from a distal end of cannula 212. Distal tip 218 is optionally adapted to puncture and penetrate the skin, soft tissue and/or cortical bone. Tip 218 may be, for example, of diamond type, drill type, bevel type or J-type, or of other tip types known in the art.

Optionally, a distal tip of the cannula is formed of a radio opaque material of different opacity and/or there is a step in diameter between the cannula and the stylet, so that transition is clearer on an x-ray image.

Optionally, stylet 214 is equipped with a proximal handle 220. In an exemplary embodiment of the invention, handles 222 and 220 engage one another via an engagement mechanism 216, for example a threaded connection. Optionally, a spring is provided to elastically couple the components. An alternative locking mechanism 217 is shown as well, in which a tongue on one handle snap-locks to a groove on the other handle. Such snap-locking may be, for example, by rotation or by axial motion.

In an exemplary embodiment of the invention, stylet 214 is rigid. Optionally, a rigid stylet supports cannula 212 during insertion and prevents deformation of cannula 212 until such deformation is desired. In an exemplary embodiment of the invention, the stylet is removed before deformation is undertaken. Optionally, a lumen of cannula 212 is adapted to comply with a diameter of stylet 214. For example, an inner cannula lumen of 2.7 mm may be provided with a stylet of 2.6 mm.

In an alternative embodiment, stylet 214 is curved. Alternatively or additionally, stylet 214 is flexible, for example, at a portion corresponding to slit series 224.

In an exemplary embodiment of the invention, stylet 214 has a preferred orientation (e.g., is beveled) which optionally matches an angled/beveled tip of the cannula.

In an exemplary embodiment of the invention designed for use in a fractured vertebral body, stylet 214 has a diameter of about 1.4-2.6 mm. It is noted that viscous material may be provided to other bone sand/or other parts of the body using the apparatus and methods described herein. The cannula optionally has an inner diameter of about 2.7 mm and an outer diameter of about 3 mm. When employed in a vertebroplasty procedure, the assembled cannula stylet 200 is introduced into the body, so distal tip 218 penetrates skin, soft tissue and vertebra. Stylet 214 is then disconnected from cannula 212 which remains in situ as described with regard to method 100 (Fig. 1).

Fig. 3A illustrates an exemplary cannula 212 with stylet 214 removed. The straight configuration of cannula 212 is optionally used for device introduction. Cannula 212 comprises a series of slits 224, which facilitate plastic deformation. Fig. 3B (inset) is an enlargement of part of series of slits 224 showing the slits in greater detail.

The pattern of the slits enlarged in Fig. 3B includes two rows of slits 226, 228 and 230, 232. The rows are displaced 180 degrees relative to each other with respect to the circumference of cannula 212. In the depicted exemplary embodiment, each row includes 12 slits, but other numbers may be provided. The slits may penetrate the cannula wall completely, or they may be perforations or grooves etched in the cannula wall.

Figs. 4A and 4B (inset) illustrate plastic deformation of cannula 212 of Figs. 3A and 3B. As seen most clearly in inset 4B, slits 230 and 232 on the inner side of the bend caused by the deformation tend to close as a result of the deformation. Slits 226 and 228 on the outer side of the bend caused by the deformation tend to remain the same size or open slightly as a result of the deformation. The closing is explained in greater detail with regards to Figs. 4C and 5.

In an exemplary embodiment of the invention, slits 226 and 228 are characterized by a width of, for example, 0.03 mm. Cannula thickness can be, for example, 0.03 mm. During plastic deformation, this width increases, for example to about 0.3 mm, for some of the slits or sections thereof (e.g., the outer slits). In the exemplary embodiment of the invention depicted in Figs. 3A; 3B; 4A and 4B, the initial width of slits in the row along the inside of the curve produced by plastic deformation (230, 232) is larger than the initial width of the slits in the row along the outside of the curve produced by plastic deformation (226, 228).

In an exemplary embodiment of the invention, cannula 212 is constructed so that the larger slits 230, 232 on the inside of the curve resulting from plastic deformation tend to close during deformation while smaller slits 226, 228 on the inside of the curve resulting from plastic deformation tend to open or stay a same width during deformation. This is described in greater detail in Fig. 4C, below.

In an exemplary embodiment of the invention, total cement leakage (or risk thereof) through the slits is less when cannula 212 is plastically deformed to a certain degree than when the cannula is straight.

Optional sleeve

Fig. 6 is a perspective view of a cannula 212 fitted with a sleeve 238 to prevent leakage of cement injected through the cannula. Sleeve 238 is deployed to cover the slits. While the sleeve is depicted on the outside of the cannula, it may optionally be provided as an inner coating. Alternatively or additionally, an external coating may be applied to cannula 212 to reduce leakage. In an exemplary embodiment of the invention, sleeve 238 adheres to cannula 212 with sufficient force to prevent or reduce leakage of bone cement being injected at pressures in the range of 100 to 300 (or 50 to 200) atmospheres. Optionally, sleeve 238 extends beyond the portion of the cannula which is slit. In an exemplary embodiment of the invention, sleeve 238 is non-compliant so that during cement injection at high pressure, the sleeve diameter remains the same. Optionally, sleeve 238 is made of a polymer with sufficient wall thickness for stability under the relevant injection pressure. Optionally, sleeve 238 is placed over cannula 212 during use (e.g., after insertion of the cannula, or prior thereto). Optionally, cannula 212 is provided with sleeve 238 in place.

In an exemplary embodiment of the invention, the slit cannula provides mechanical support for the sleeve, which may be, for example, coated on or adhered to the cannula.

In some cases, additional strengthening may be desired, for example, by providing an additional sleeve over the sleeve, or by providing compression rings which prevent flow out between the sleeve and the cannula body, at the sleeve edge. Optionally, a compression ring is provided for each set of or for more than one set of slits.

In an exemplary embodiment of the invention, an inner coating is provided to reduce friction between the cement and the cannula. Alternatively or additionally, an outer coating is provided to prevent adhesion of the cannula to hardening cement. Such coatings may also serve to reduce leakage. An exemplary thickness is 0.1 mm.

Optionally, one or more of chemical resistance (to cement), friction reduction and/or sticking prevention are provided by a cover. Exemplary cover materials include PTFE, ETFE,

PFA, or FEP – Teflon® or other materials with suitable properties. Optionally, a heat-shrinking sleeve is used, which may be heat shrunk while manufacturing or after bending (e.g., with a heat gun).

Bending location

In an exemplary embodiment of the invention, series of slits 224 deployed on cannula 212 designed so that they are located substantially or wholly outside a patient body during use, for example, at least 60%, at least 75% or more of the deformable area is outside the patient. Optionally, plastic deformation of cannula 212 bends the cannula towards the surgeon so that attachment of a cement reservoir is convenient. In an exemplary embodiment of the invention, a marking (not shown in the Figure) on cannula 212 indicates preferred deformation orientation (e.g., toward larger cuts 230, 232).

In an exemplary embodiment of the invention, the deforming area is selected to reduce kinking of the cannula and/or reduce the amount of bending at each point and thus the local straightening force applied when injecting cement.

In an exemplary embodiment of the invention, the length of the cannula between the deforming area and the distal tip is between 100 mm and 150 mm. Optionally, 100 mm is used for the upper spine and 150 for the lower back.

In an exemplary embodiment of the invention, the use of a bending cannula allows the cement reservoir to be closer to the bone. Reduction in distance may be useful, for example, for one or more of reducing resistance to flow, reducing dead volume of cement and/or for reducing temperature changes of the cement as it flows. Optionally, the use of a bending cannula obviates the need for a separate short flexible tube and its associated connectors and possible need for manual manipulation. In an exemplary embodiment of the invention, the total length of the cannula including the bending region is for example, 150 mm, for example, 100 mm straight and 50 mm bending. A longer straight and/or bending area may be provided, for example, to give a cannula length of 200 mm.

Self-penetrating cannula

Fig. 7 illustrates an exemplary embodiment of a cannula 712 with a radial injection aperture 710 and a penetration tip 720. Penetration tip 720 optionally serves in place of stylet tip 218 as described above. A separate stylet may be provided for ensuring that cannula 712 does not bend during insertion. In some embodiments, no stylet is used.

Optionally, multiple fill ports are provided, for example as described below.

Multiple ports and/or a penetrating tip are optionally provided with any of the cannula designs described herein.

Detailed exemplary slit design

Fig. 4C shows a detail of an exemplary slit design, in accordance with an exemplary embodiment of the invention. In the detail shown, there are two slits, 228 (from the outer bend) and 232 (from the inner bend). Slit 228 includes a base cut 246 and a beam cut 248. As shown in Fig. 5, a second base cut may be provided on the other side of the cannula. Slit 232 includes a base cut 236 and a beam cut 244.

In an exemplary embodiment of the invention, the various slits define a portion 240 in the general shape of a rectangle that is defined by the base cuts (and the lines connecting them) which is plastically deformed when the cannula is deformed. In some cases, the deformation extends a short distance away from the cuts/rectangular area, for example, from the base cuts. In an exemplary embodiment of the invention, portion 240, even if deformed is robust enough to maintain the deformed configuration of the cannula. In an exemplary embodiment of the invention, portion 240 acts as a bending bar.

In an exemplary embodiment of the invention, base cut 246 serves to limit the deformation to portion 240 and/or guide the deformation region. Optionally, the edges of base cut 246 and/or base cut 236 are rounded to prevent tearing and/or reduce stress concentrations.

In an exemplary embodiment of the invention, when bent towards slit 232, beam cut 244 tends to close. Optionally, beam cut 244 is pre-formed to be open, so that it can close lip to lip.

In an exemplary embodiment of the invention, base cut 236 tends to close when the cannula is bent and includes a cut-out so as to facilitate lip to lip matching. Optionally, the cuts are not straight lines, but curved in anticipation of lip-to-lip meeting in a deformed configuration.

In an exemplary embodiment of the invention, the bending of the cannula envelope is at beam cut 248, so that there is less strain in the cannula.

In an exemplary embodiment of the invention, at least some of the cuts may be replaced by other weakening methods, for example, etching, chemical treatment, thinning and/or heat treatment. Alternatively or additionally, elongation properties of plastically deforming areas may be enhanced to reduce and/or prevent tearing.

In an exemplary embodiment of the invention, beam cut 248 is provided as a weakened area. Optionally, some of portion 240 is weakened. Optionally, the weakened area is selected so that crumpling and possible kinking of the cannula lumen are avoided.

While the figure shows a symmetric design with opening at one side and closing at the other, this is not essential. For example, the amount of resistance to bending at either side need

not be equal. In one example, slit 228 does not exist and part of portion 240 is weakened to facilitate deformation thereof when slit 232 is closed by the deformation of the cannula. Optionally, one or more wedge sections are removed from portion 240, instead of weakenings, extending from base cut 236 towards base cut 246 (which need not exist in this embodiment).

In another example, the slit design comprises only a wedge shaped slit generally aligned with beam cut 244 and narrowing in the direction of the outside of the bend. At the tip of the slit, a strain relief cut-out is optionally provided. Optionally, a plain slit on the outside bending side of the cannula is provided.

In an exemplary embodiment of the invention, the exact shapes, dimensions and/or mechanical properties of the cuts and nearby regions are determined using finite element software. For example, by setting the thickness of the cannula and searching for values for the dimensions of portion 240 and/or selecting amount various shapes and/or other parameters until a best solution is found. Optionally, a best solution is one with minimal working, minimal chance of tearing, minimal leakage potential and/or minimal narrowing of the lumen by buckling.

In an exemplary embodiment of the invention, the cannula is made of metal (e.g., stainless steel 304 or 316), as this typically allows a bigger inner diameter for a same outer diameter.

Fig. 5 is a plan view of a bendable cannula. As can be appreciated, the final geometry of the cannula typically depends not on a single slit area as shown in Fig. 4C, but on a plurality of such slit areas. In an exemplary embodiment of the invention, the series of slits is selected to achieve a desired final geometry. It is noted that the deformation need not match this geometry, for example, by providing more or less deformation. However, in an exemplary embodiment of the invention, the design is optimized for one or more deformation configurations.

In an exemplary embodiment of the invention, the deformation is that of a simple bending. Such deformation is optionally facilitated by providing multiple slit sections to act as joints (bending areas). These sections are optionally provided as equal-design joints, each of which bends about a same amount, for example 10 degrees, in the same direction (e.g., same bending direction. The distance between the joints can be used to set the bending radius. For example, a length of deformable area of 30 mm can provide a 19 mm bending radius for a 90 degree bend. In an exemplary embodiment of the invention, the cannula is designed for a 130 degree bend, which will allow resting of the cement reservoir on the patient's back. Optionally, a bend of about 90 degrees is provided, for example, to move the cement reservoir out of a line of sight of an x-ray imager. Optionally, the degree of bending varies among the joints, for

example, increased bending per joint being provided at one or the other end of the deformable area and/or at a center thereof.

In an exemplary embodiment of the invention, the deformation is not a plain curve. For example, an S-shaped curve can be provided if a first series of joints face one way and a second series of joints face another way. A non-planar (3D) deformation can be facilitated if the base cuts do not all lie on a line parallel to the cannula axis, for example lying on a spiral or lying on two or more such parallel or non-parallel lines..

Optionally, the cannula is pre-bent and then cut, so the joints define a deformation on a curved element, rather than on a straight element. Optionally, such joints define a straightened (or straighter) configuration of the cannula.

Fig. 5 also illustrates that each slit (e.g. 232) comprises a beam cut 244 and two base cuts, 234 and 236. Optionally, these base slits improve stress distribution along the length of cannula 212. Optionally, greater stress distribution reduces unwanted crimping of walls of the cannula.

While specific numbers, shapes and distributions/arrangements of slits are depicted in the figures and text, it is stressed that the scope of the invention any number and/or arrangement and/or shape and/or dimensions and/or spacing of slits employed to facilitate plastic deformation of a bone cement cannula. In an exemplary embodiment of the invention, the slits are distributed along the entire length of cannula 212, rather than the proximal part only. Optionally, an offset of at least 5 mm, at least 10 mm or more is provided between the last joint and the connector. Optionally, this area is used to anchor the above described optional flexible sleeve.

In an exemplary embodiment of the invention, the configuration of cannula 212 after bending is such that the cement (or other viscous material) flows in a non-straight path (e.g., curved path or piecewise linear) for a substantial distance. A potential advantage over a pivoting design, where a single joint provides a large angular change between parts of the cannula is that at each point in the non-straight path, the straightening forces may be small. Alternatively or additionally, flow of non-fluids may be facilitated by gradual direction changes. Alternatively or additionally, the mechanism for pivoting (e.g., with an alignment of the flow path with the pivot center) may be complicated. Alternatively or additionally, leakage at integral metal joints with small angles may be relatively small (and in some cases ignored). Alternatively or additionally, deformation of metal at small angles is possible, potentially allowing complicated (to make) joints to be dispensed with and formed directed out of the cannula body.

Supported deformation

Cannula 212 is an example of a cannula where the cannula body itself provides support for the deformed configuration of the cannula. In alternative embodiments, this is not the case.

Figs. 8A and 8B show a cannula 812 including a deformable section 820, a rigid section 826 ending at a tip 710, and a connector 828, for providing cement into the cannula. Fig. 8A shows cannula 812 in a straight configuration and Fig. 8B shows cannula 812 in a bent configuration.

In an exemplary embodiment of the invention, deformable section 820 comprises a flexible tube 824 and a construct which sets a bending state of the tube.

In an exemplary embodiment of the invention, as pictured, this construct comprises one or more bars 870 and 880, coupled to either side of tube 824. In the example shown a first block 860 is provided at one side of the tube and is pivotally attached to bars 870, 880, for example, using one or more pins 822. A second block 850 is provided at a second end of the tube and is attached to bars 870, 880, using a sliding attachment, for example, with one or more sliding pins 830. Optionally, each side of the tube has one sliding and one pivoting pin. In an exemplary embodiment of the invention, the friction of the sliding connection and/or the pivoting connection are set to resist straightening forces, while allowing manual deformation.

In an exemplary embodiment of the invention, bars 870 and 880 serve to resist twisting forces associated with inserting and/or removing the cannula from the body.

An alternative construct is that of a goose-neck covering for tube 824 (goose-neck not shown). Another alternative construct is a tube of plastically deformable material. Another alternative construct is a providing one or more metal wires which are malleable. Such wires may be provided, for example, outside of tube 824 or embedded therein.

Flexible connector

Fig. 9A is a cross-sectional side view of a cannula 912 including a flexible section 900. Optionally, the flexible section is thicker than the rest of the cannula, but being outside the body, this may be acceptable. Optionally, a tissue stop 902 is provided, for example, as a rigid ring or as a movable ring, which prevents penetration of section 900 into the body. Section 900 can be, for example, a deformable section as described above.

Fig. 9B shows cannula 912 in a bent configuration, without optional tissue stop 902.

Method of manufacture

Fig. 11 is a flowchart of an exemplary method 1100 of manufacture of a deformable cannula in accordance with exemplary embodiments of the invention.

At 1110, a work piece is provided, for example, a flat metal sheet, a metal tube, a tube with an end formed thereon and/or a tube with a handle fitted thereon. Optionally, a long tube suitable for multiple cannulae is provided. In some embodiments, the cannula is formed of a polymer, rather than a metal tube.

At 1120, the work piece is engaged by a cutting device including control circuitry, for example, a computer.

At 1130, the cutting device is programmed for cutting a desired pattern, for example, by etching, laser cutting, water cutting, e-beam cutting, machining, abrasion and/or other metal working methods known in the art. Optionally, the device is preprogrammed.

At 1140 the program is executed to form the slits and/or other weakenings. Optionally, the program also forms cement inlet and/or outlets.

Optionally, laser heating and/or electron-beam heating are used to anneal portions 240, and thereby improve their ductability. This may be done on a same device or on a different device.

At 1150, the deformable cannula is removed from the cutting device. Optionally, a handle is attached. Optionally, if the work piece was provided as a sheet, it is now welded or otherwise formed into a tube.

Distal aperture

Fig. 12 is a schematic side cross-sectional view of a sealed-tip cannula 1200, with an axial aperture 1202 for a stylet 1204, in accordance with an exemplary embodiment of the invention. A second, side exit port 1206, is shown for exit of cement.

In an exemplary embodiment of the invention, aperture 1202 is smaller than a grain size of the cement used and/or is small relative to a viscosity of the cement used, so there is little leakage there through once stylet 1204 is removed. In an exemplary embodiment of the invention, the ratio of cement flow through the axial aperture and the side port(s) is better than 3:1, better than 4:1, better than 6:1, better than 10:1 or intermediate values.

In an exemplary embodiment of the invention, the area ratio between the aperture and the port is at least 1:5, 1:8, 1:10, 1:15, 1:20 or intermediate or greater values. Such ratios may reduce the leakage.

Alternatively or additionally, a closing mechanism is provided. In one example, a plug (not shown) is pushed along the stylet and plugs aperture 1202. Optionally, the plug is provided as a forward part of the cement delivery system. Optionally, such a plug travels along a bent cannula and is too wide to exit through side exit port 1206.

In another example, a trap-door mechanism 1208 is provided which closes, either on its own or due to cement pressure, once stylet 1204 is removed.

In another example, a plug 1210, for example, a ball, is attached to the inside of the cannula and plugs aperture 1202 when cement flows thereto.

Multiple loading ports

In an exemplary embodiment of the invention, a cannula is provided with multiple loading ports. This may be useful for a non-deforming cannula, where an axial loading port is used for entry of a stylet and a side loading port is provided for injecting cement without a cement delivery system blocking a line of sight of a doctor and/or imaging system and/or without applying torque to the patient. Typically, cement is injected after the stylet removed.

An alternative reason for providing multiple ports is that it may be desirable to provide a plurality of materials into the patient (e.g., bone cements of varying viscosities), without detaching a high-pressure (or other) delivery system. An alternative reason for providing multiple ports is for pressure relief at the cannula.

Fig. 10A shows a cannula 1002 including an axial port 740 and a side port 730. Fig. 10B shows that after use of the axial port, it may be closed using a cap 1010, for example, a threaded cap. A similar cap may be used for side port 730.

Fig. 10C (axial open) and Fig. 10B (axial closed), show a trap-door valve 1020 which selectively closes an axial port 740 of a cannula 1004. A potential advantage of a trap-door valve is that backpressure closes it and/or may assist in sealing it. Thus, for example, entry of cement through port 730 will tend to close door 1020 and thus seal port 740. Application of a greater pressure at port 740, will reopen the port.

In an exemplary embodiment of the invention, the trap-door does not lie flush with the cannula inner surface. Rather a space (not shown) is provided between the door and the surface, for example, a wedge shape space, to ensure that flow of cement from port 730 will close the door, rather than force it to remain open. Alternatively or additionally, an elastic closing hinge is used.

Fig. 10E (axially open) and Fig. 10F (axially closed) show a cannula 1006, in which a rotating valve, such as a stopcock valve, selectively makes one of the ports patent.

Other tissue and general comments

While the above application has focused on the spine, other tissue can be treated as well, for example, compacted tibia plate and other bones with compression fractures and for tightening implants, for example, hip implants or other bone implants that loosened, or during

implantation. Optionally, for tightening an existing implant, a small hole is drilled to a location where there is a void in the bone and material is extruded into the void.

It should be noted that while the use in bones of the above methods and devices provide particular advantages for bone and vertebras in particular, optionally, non-bone tissue is treated, for example, cartilage or soft tissue in need of treatment. Optionally, the delivered material includes an encapsulated pharmaceutical and is used as a matrix to slowly release the pharmaceutical over time. Optionally, this is used as a means to provide anti-arthritis drugs to a joint, but forming a void and implanting an eluting material near the joint. In an exemplary embodiment of the invention, the eluting material is of a high viscosity and or is a soft non-flowing material.

In another embodiment, the injected material is a nucleus for a disc.

It will be appreciated that the above described apparatus and methods of implanting and treating may be varied in many ways, including, changing the order of steps, which steps are performed more often and which less often, the arrangement of elements, the type and magnitude of forces applied and/or the particular shapes used. In particular, various tradeoffs may be desirable, for example, between applied forces, degree of resistance and forces that can be withstood. Further, the location of various elements may be switched, without exceeding the spirit of the disclosure, for example, the location of the cement outlet. In addition, a multiplicity of various features, both of method and of devices have been described. It should be appreciated that different features may be combined in different ways. In particular, not all the features shown above in a particular embodiment are necessary in every similar exemplary embodiment of the invention. Further, combinations of the above features are also considered to be within the scope of some exemplary embodiments of the invention. In addition, some of the features of the invention described herein may be adapted for use with prior art devices, in accordance with other exemplary embodiments of the invention. The particular geometric forms used to illustrate the invention should not be considered limiting the invention in its broadest aspect to only those forms, for example, where a cylindrical tube is shown, in other embodiments a rectangular tube may be used. Although some limitations are described only as method or apparatus limitations, the scope of the invention also includes apparatus programmed and/or designed to carry out the methods.

Also within the scope of the invention are surgical kits which include sets of medical devices suitable for delivering cement or other viscous materials and suitable material. Section headers are provided only to assist in navigating the application and should not be construed as necessarily limiting the contents described in a certain section, to that section. Measurements

are provided to serve only as exemplary measurements for particular cases, the exact measurements applied will vary depending on the application. When used in the following claims, the terms "comprises", "comprising", "includes", "including" or the like means "including but not limited to".

It will be appreciated by a person skilled in the art that the present invention is not limited by what has thus far been described. Rather, the scope of the present invention is limited only by the following claims.

CLAIMS

1. A bone cement cannula, the cannula comprising:

(a) a tube including a section adapted for plastic deformation;

(b) a lumen in the tube capable of resisting forces of a viscous material propelled therethough at a pressure of at least 100 atmospheres.

2. A cannula according to claim 1, wherein said section adapted for plastic deformation comprises a series of separate joints formed in an outer wall of the cannula.

3. A cannula according to claim 2, wherein at least one of said joints is formed by at least one cut.

4. A cannula according to claim 3, wherein at least one of said cuts is configured to close as the cannula deforms.

5. A cannula according to any of claims 2-4, wherein at least one of said joints is formed by non-penetrating weakening of the cannula wall.

6. A cannula according to any of claims 2-5, wherein said joints facilitate a desired deformation configuration of the cannula.

7. A cannula according to any of claims 2-6, wherein said joints are sealed.

8. A cannula according to any of the preceding claims, comprising an outer sealing layer.

9. A cannula according to any of the preceding claims, comprising an inner sealing layer.

10. A cannula according to any of the preceding claims, wherein said section is adapted to remain outside of a body.

11. A cannula according to any of the preceding claims, wherein said section adapted for plastic deformation comprises a deformable sleeve.

12. A cannula according to any of the preceding claims, wherein said section adapted for plastic deformation comprises a flexible tube and a configuration support for said tube.

13. A cannula, comprising:

(a) a tube including a section adapted for plastic deformation;

(b) a lumen in the tube, said lumen at least partially filled with a bone filling material.

14. A bone cement cannula, the cannula comprising:

(a) a tube including a tube lumen providing a channel of fluid communication between at least one injection aperture and a connector body; and

(b) at least two inlet ports defined in said tube.

15. A cannula according to claim 14, wherein one of said ports is axially oriented.

16. A cannula according to claim 14 or claim 15, wherein at least one of said ports is trans-axially oriented.

17. A cannula according to any of claims 14-16, including a port path selector adapted to selectively allow flow from one of said ports.

18. A cannula according to any of claims 14-17, including a port path blocker adapted to selectively allow block back-flow out of one of said ports.

19. A manufacturing process for a surgical tool, the process comprising:

(a) determining a pattern of cuts which will impart a desired deformability to a work piece;

(b) imparting the desired plastic deformability to the work piece by incising the pattern of cuts therein to produce a surgical tool; and

(c) forming said work piece into a cannula suitable for bone cement injection.

20. A method of delivering cement, comprising:

(a) providing a cannula with an axial guide-wire exiting through an axial hole thereof and said cannula including a side exit port;

(b) inserting said cannula into a bone;

(c) removing said stylet; and

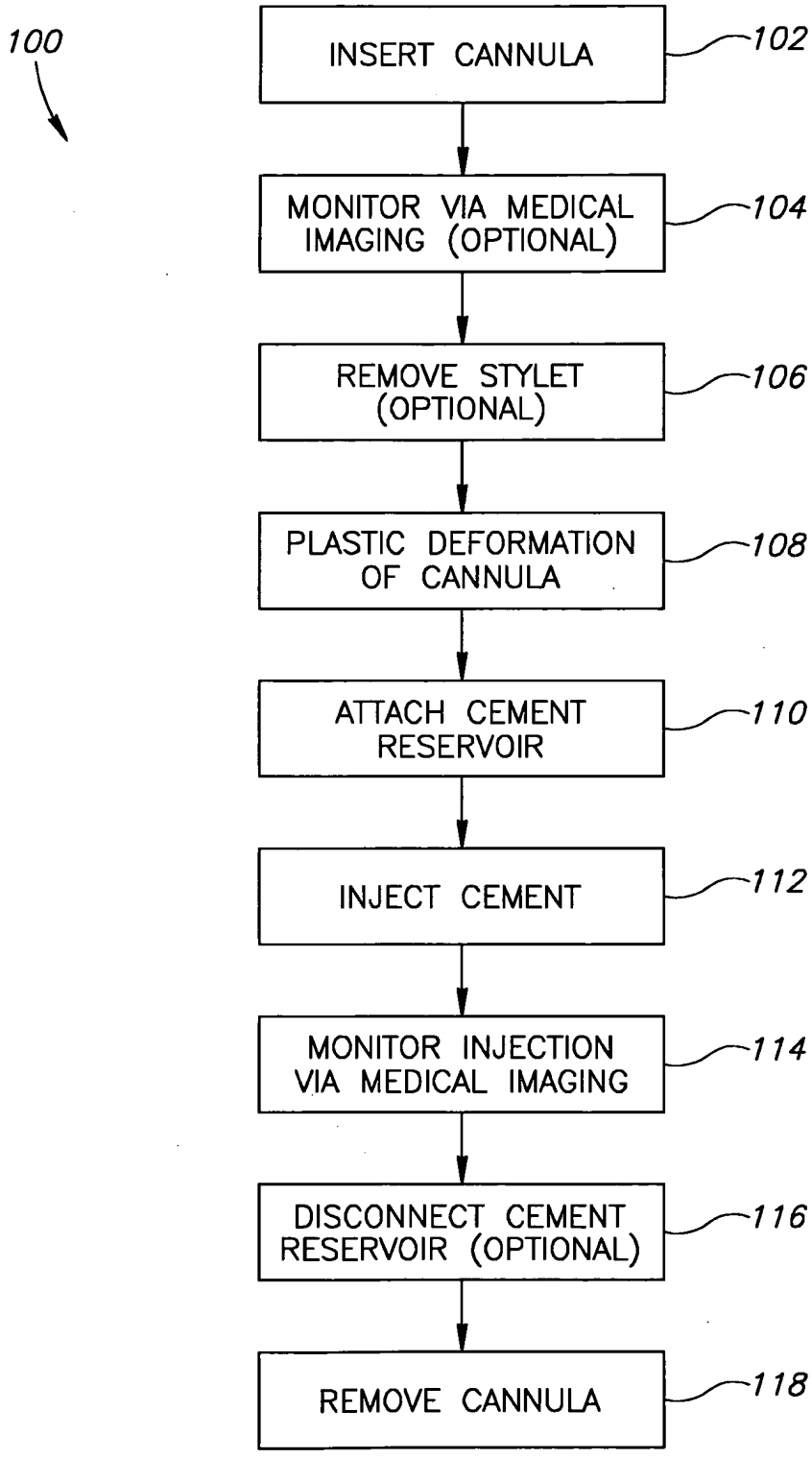
(d) injecting cement through said cannula such that less than 20% of the cement exits through the axial hole.

21. A method of injecting a viscous material into a patient, comprising:

(a) inserting a cannula into a patient;

(b) bending said cannula over a length of at least 20 mm; and

(c) injecting a viscous material through said cannula.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INSERT CANNULA
102
MONITOR VIA MEDICAL IMAGING (OPTIONAL)
104
REMOVE STYLET (OPTIONAL)
106
PLASTIC DEFORMATION OF CANNULA
108
ATTACH CEMENT RESERVOIR
110
INJECT CEMENT
112
MONITOR INJECTION VIA MEDICAL IMAGING
114
DISCONNECT CEMENT RESERVOIR (OPTIONAL)
116
REMOVE CANNULA
118

FIG.1

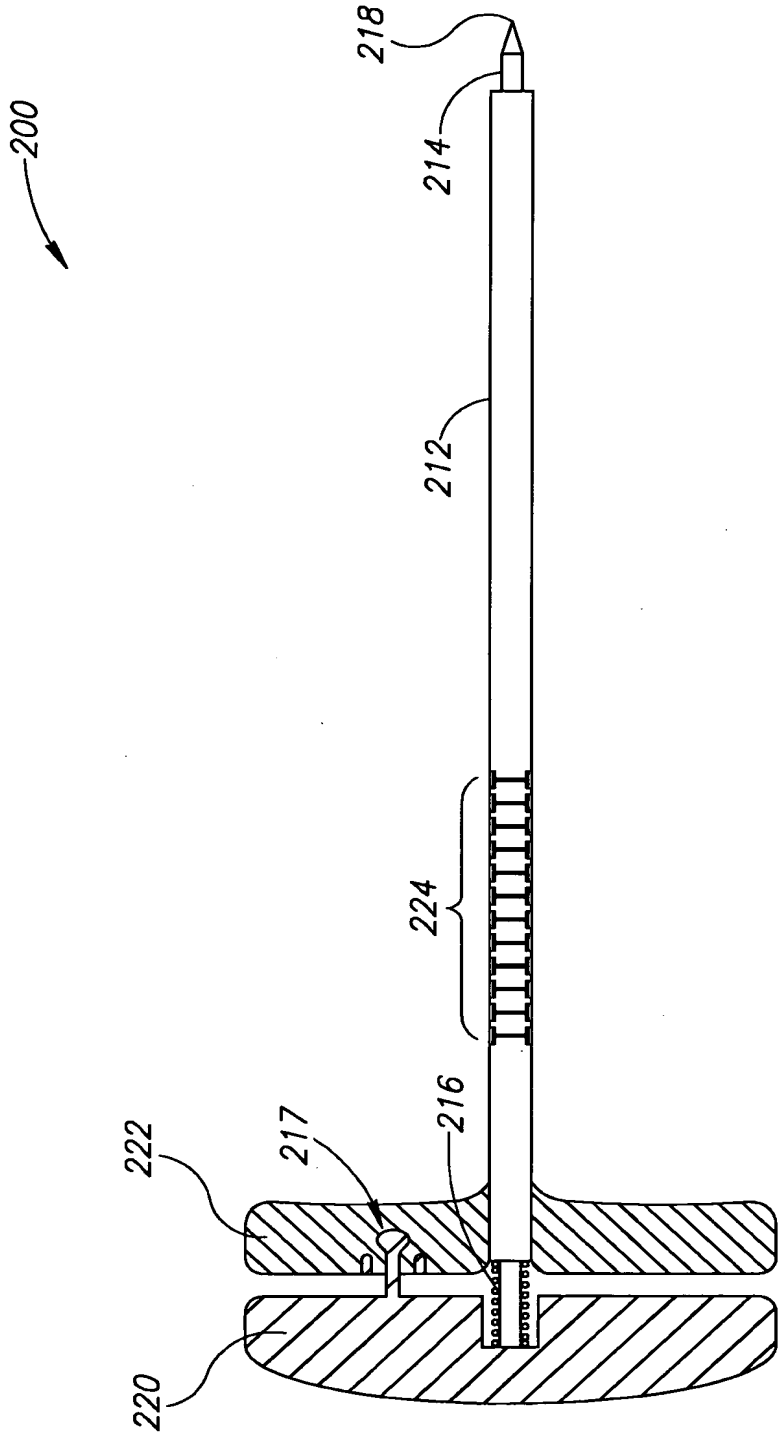


FIG.2

FIG.3A

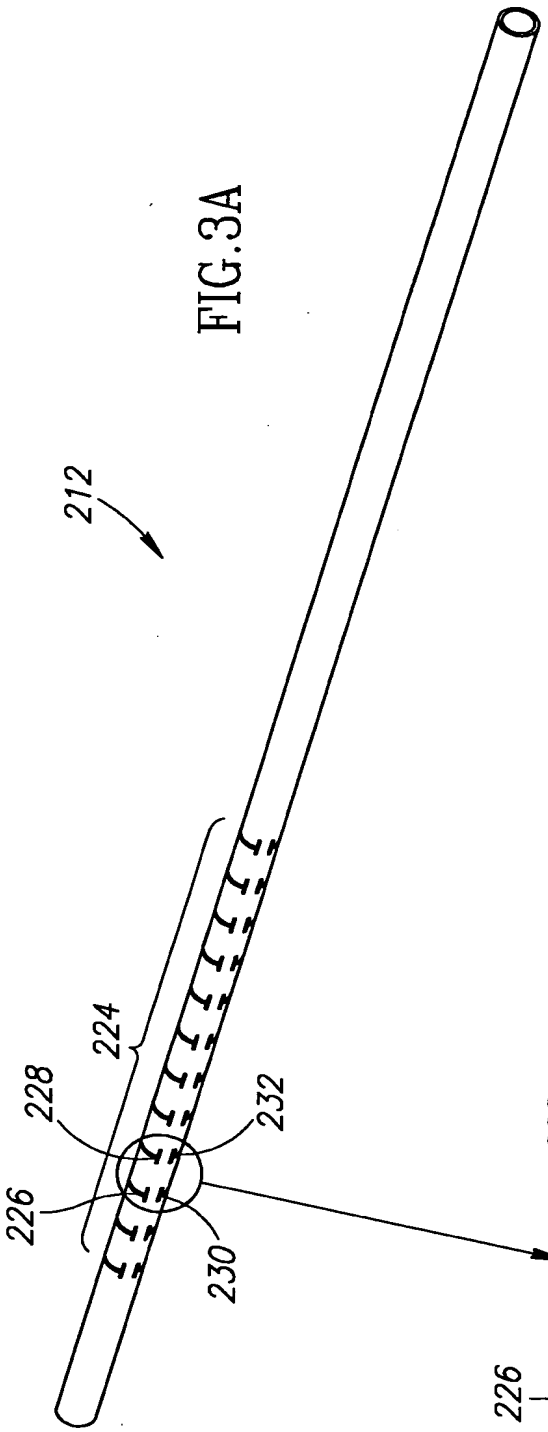
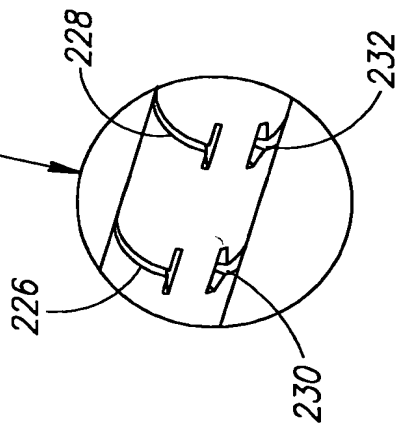


FIG.3B



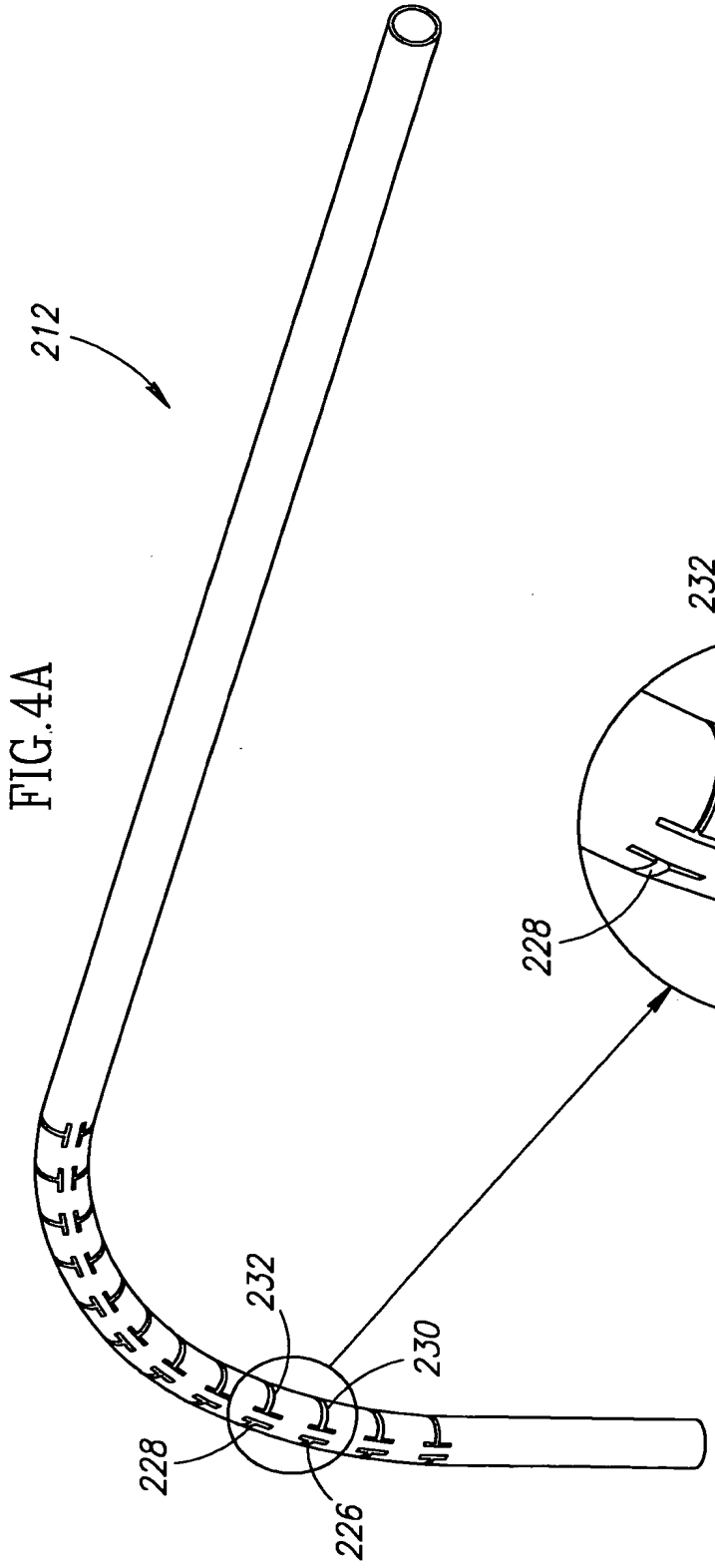


FIG.4A

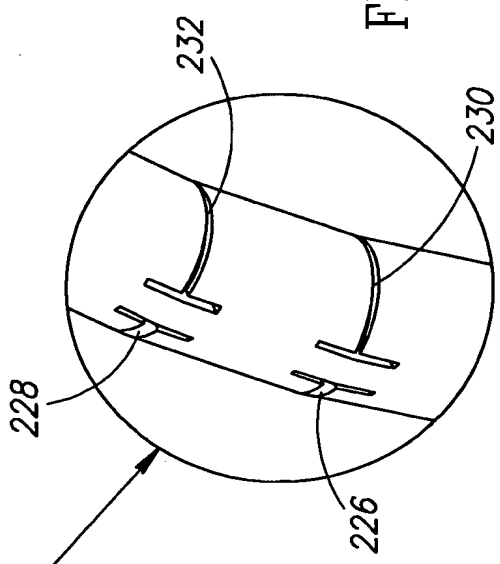


FIG.4B

FIG.4C

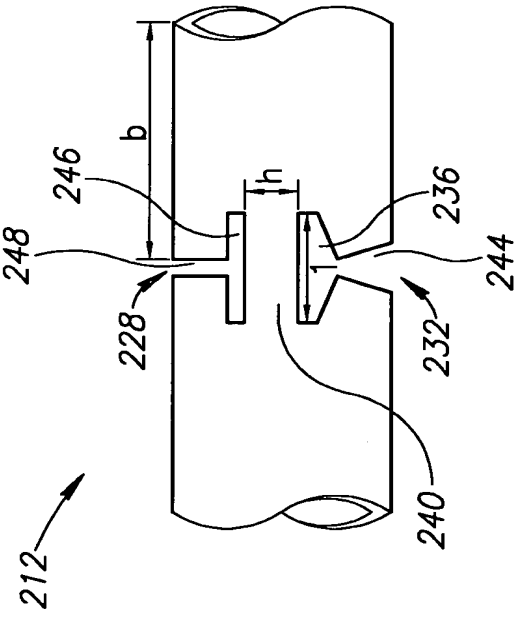
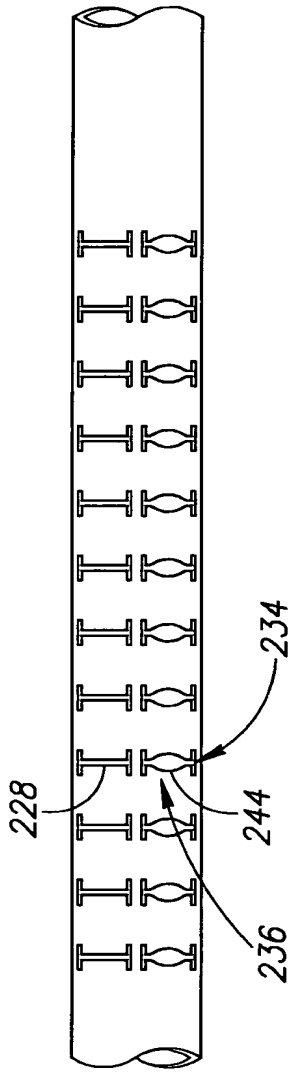


FIG.5



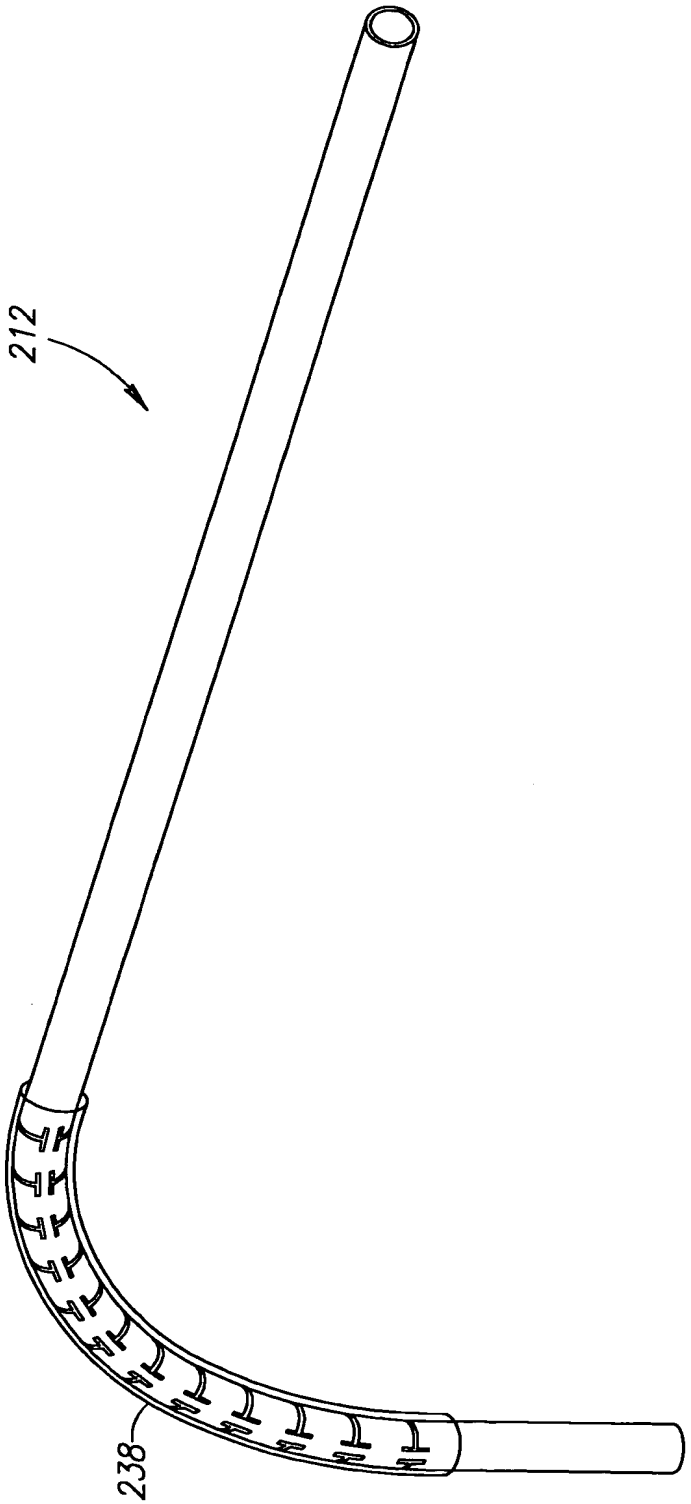


FIG.6

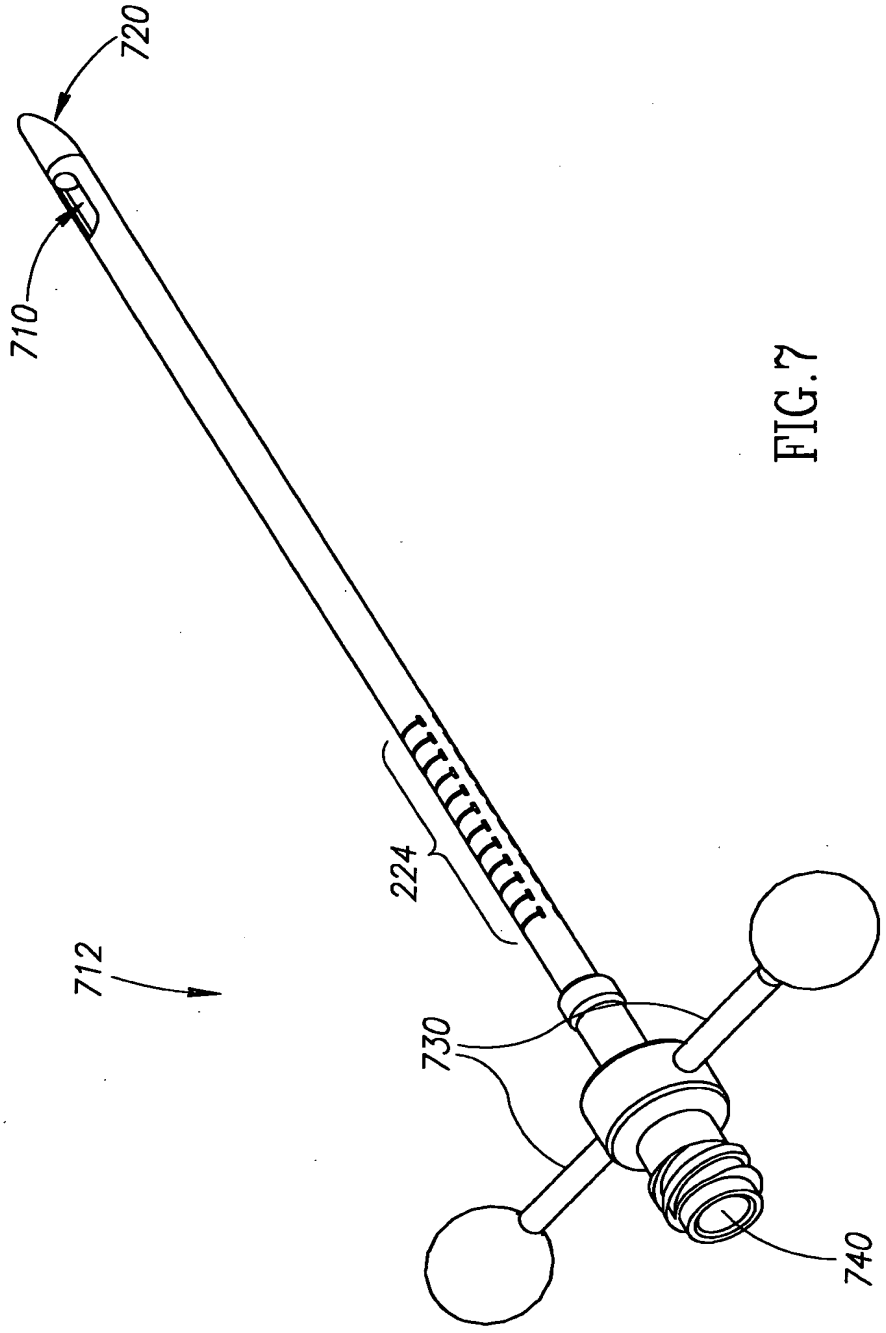


FIG.7

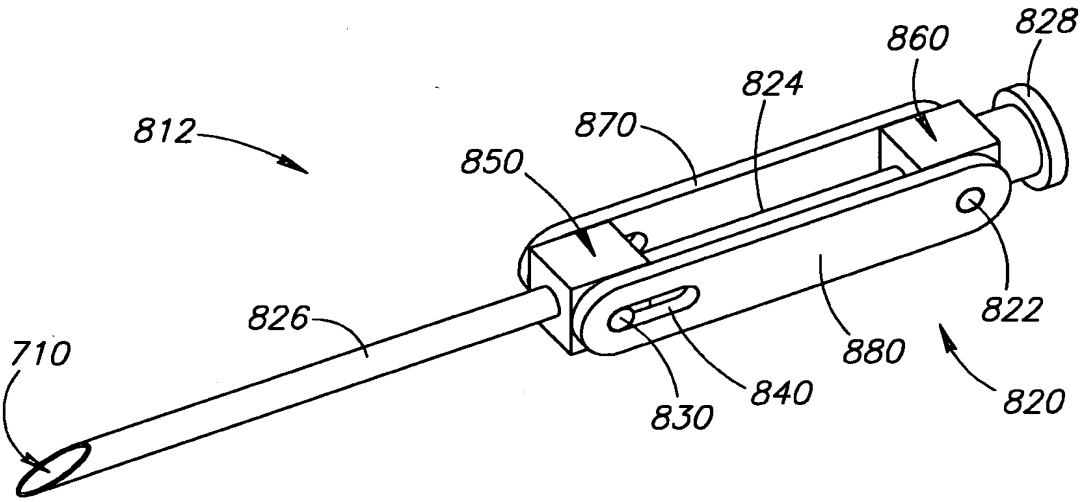

812
850
870
824
860
828
826
710
822
880
820
830
840

FIG.8A

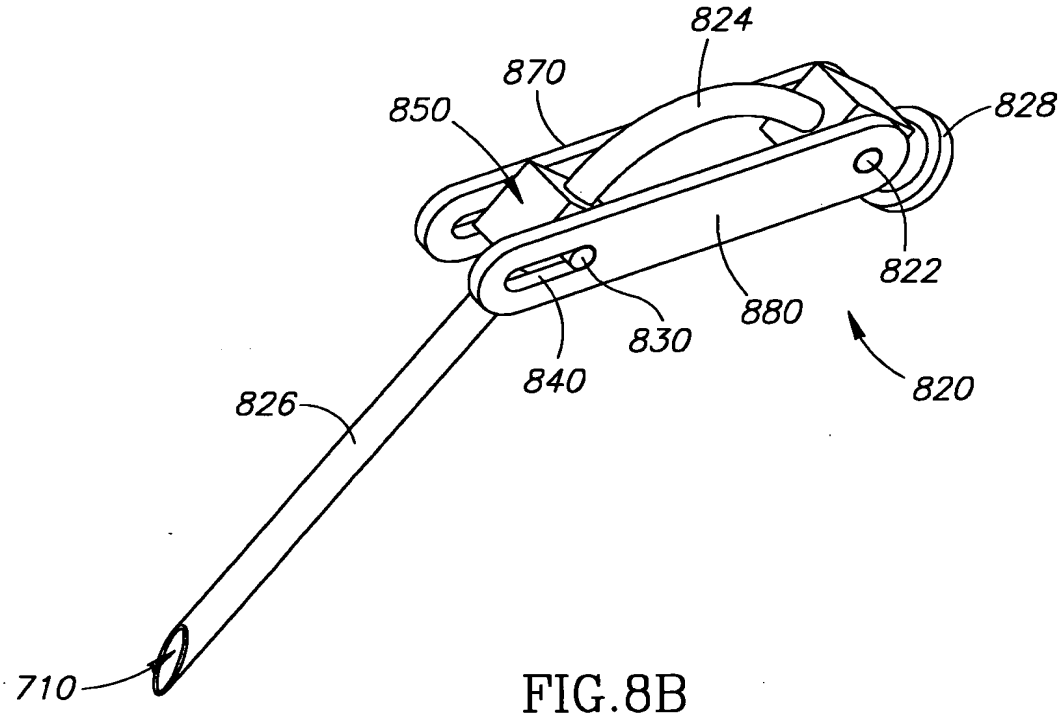

824
870
850
828
822
880
830
840
826
820
710

FIG.8B

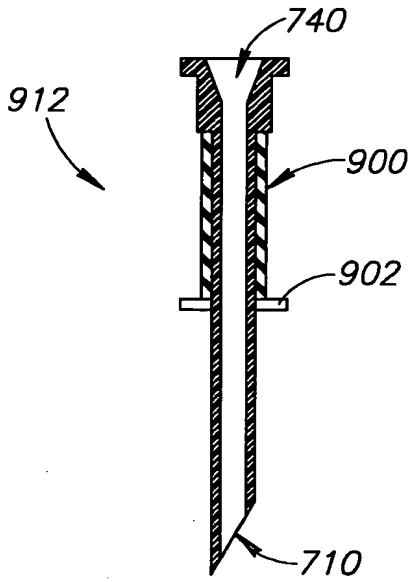


FIG.9A

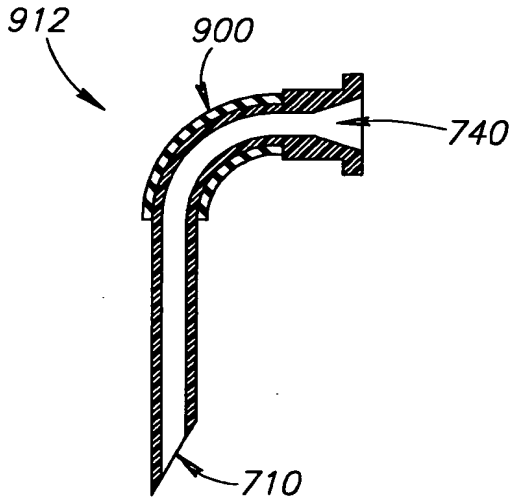


FIG.9B

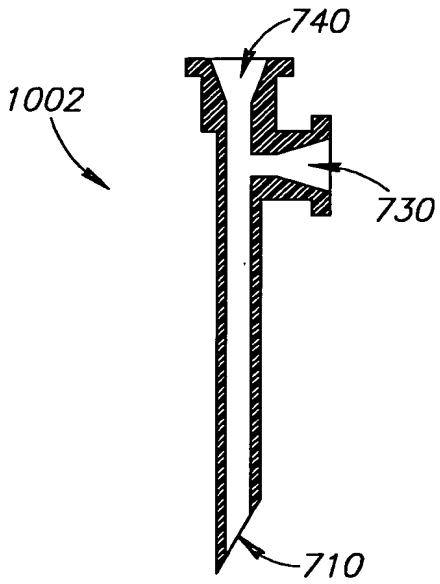


FIG.10A

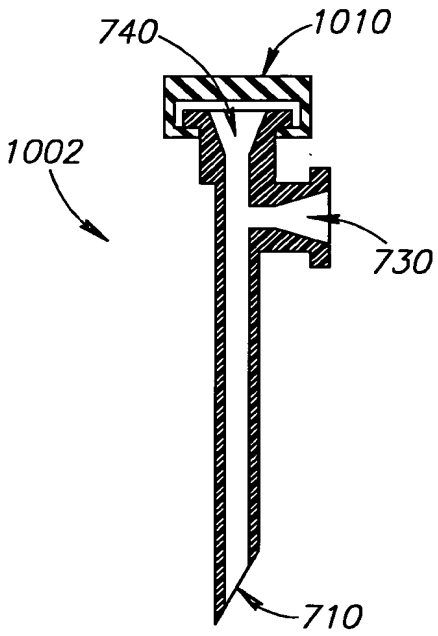


FIG.10B

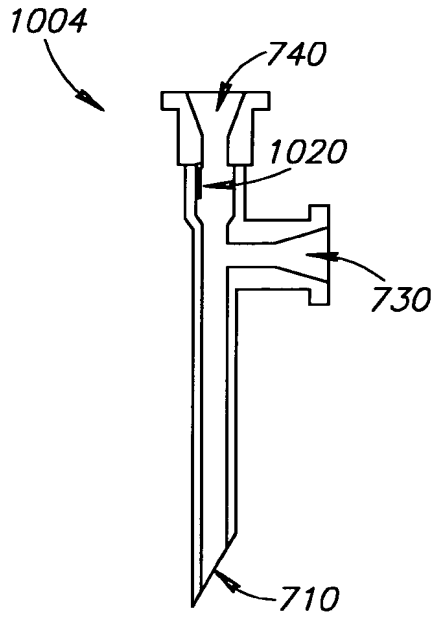


FIG.10C

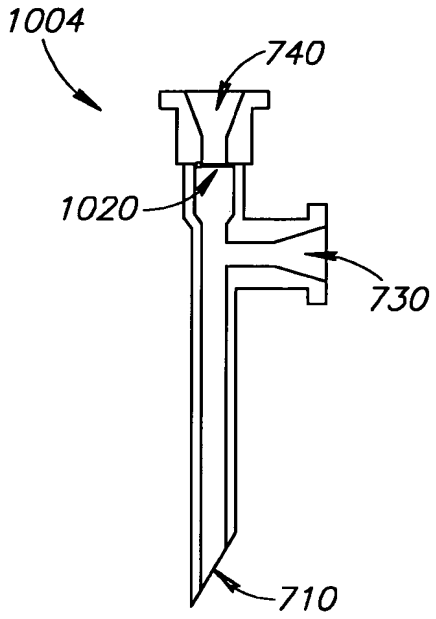


FIG.10D

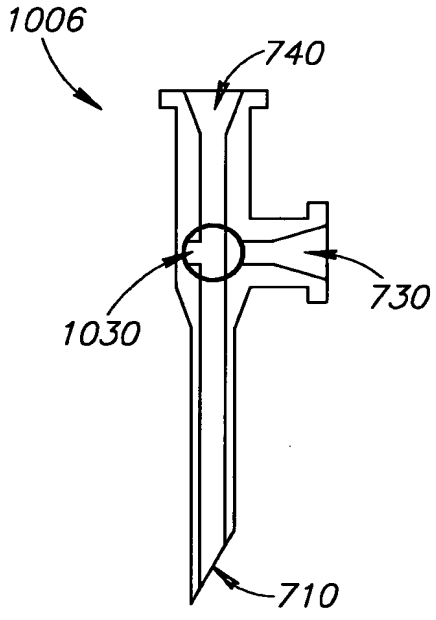


FIG.10E

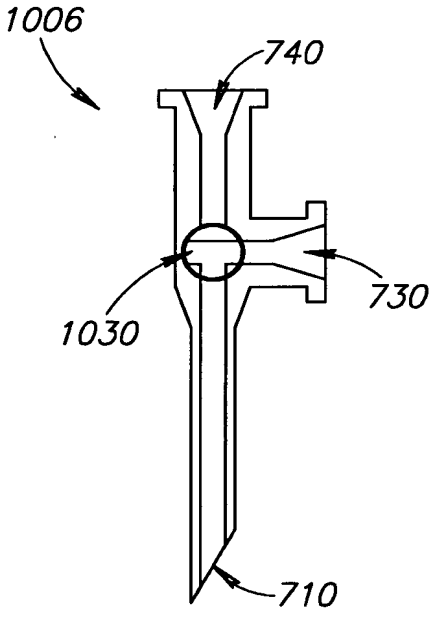


FIG.10F

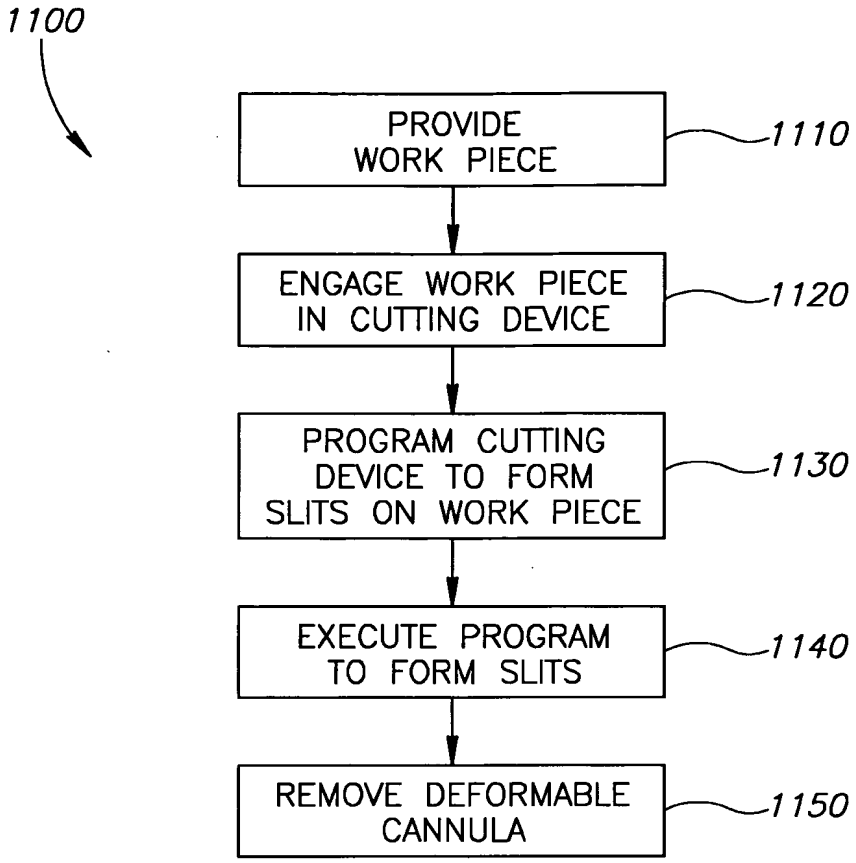

1100
PROVIDE WORK PIECE
1110
ENGAGE WORK PIECE IN CUTTING DEVICE
1120
PROGRAM CUTTING DEVICE TO FORM SLITS ON WORK PIECE
1130
EXECUTE PROGRAM TO FORM SLITS
1140
REMOVE DEFORMABLE CANNULA
1150

FIG.11

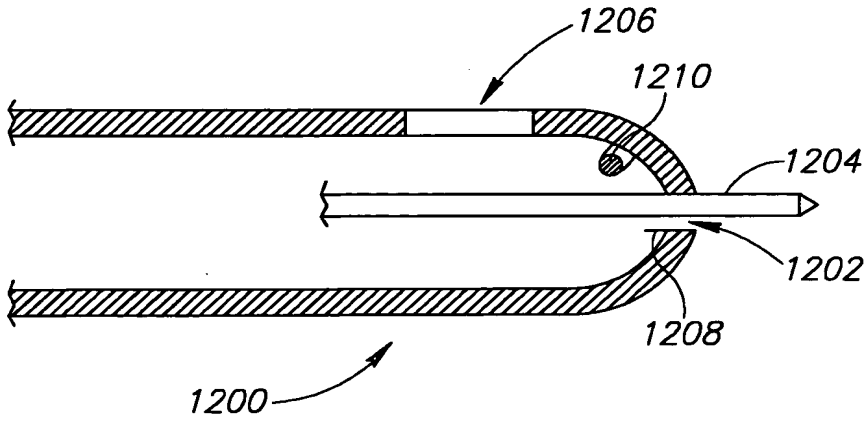

1206
1210
1204
1202
1208
1200

FIG.12

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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(30) Priority Data:

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60/763,003	26 January 2006 (26.01.2006)	US
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11/360,251	22 February 2006 (22.02.2006)	US

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(72) Inventors; and
(75) Inventors/Applicants *(for US only)*: **BEYAR, Mordechay** [IL/IL]; 7 Haeshkolit Street, 38900 Caesarea (IL). **GLOBERMAN, Oren** [IL/IL]; 30 Derech Haganim Street, 46910 Kfar-Shmaryahu (IL).

(74) Agents: **FENSTER, Paul** et al.; Fenster & Company, Intellecutual Property Ltd., P. O. Box 10256, 49002 Petach Tikva (IL).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LV, LY, MA, MD, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, SV, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

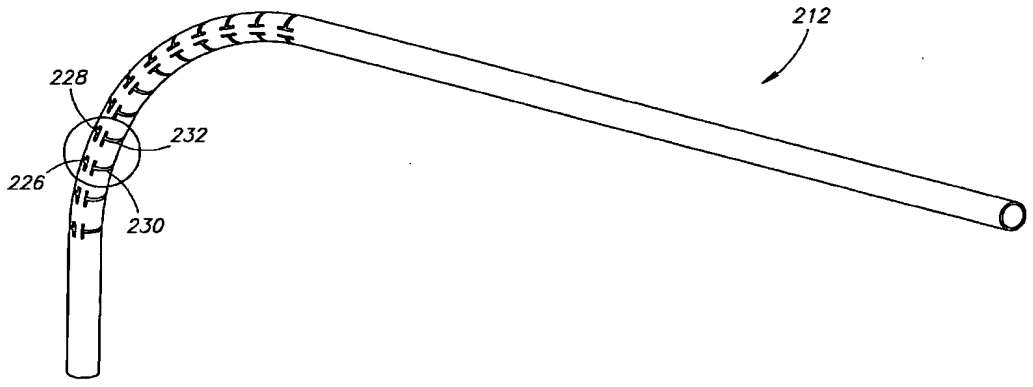
Declaration under Rule 4.17:
— *of inventorship (Rule 4.17(iv))*

Published:
— *with international search report*

(88) Date of publication of the international search report:
13 September 2007

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: CANNULA FOR INJECTING MATERIAL INTO BONE



(57) Abstract: A bone cement cannula, the cannula comprising: a tube (212) including a section (224) for plastic deformation; and a lumen in the tube capable of resisting forces of a viscous material propelled therethrough at a pressure of at least 100 atmospheres. Alternatively a bone cement cannula (1002) with at least two inlet ports (730) , (740) for a plurality of materials or entry of a stylet.

WO 2007/036815 A3

INTERNATIONAL SEARCH REPORT

International application No
PCT/IB2006/053014

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B17/34

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61B A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2004/260303 A1 (CARRISON H.F.) 23 December 2004 (2004-12-23) cited in the application	1,10,12, 13
Y	paragraphs [0002] - [0004], [0006], [0008], [0009], [0024], [0028], [0039], [0040]; figure 1	2-9,11, 19
X	WO 2005/051212 A (SOMATEX MEDICAL TECHNOLOGIES) 9 June 2005 (2005-06-09)	1,10,12, 13
A	page 10, line 23 - line 28; claim 3; figure 1	2-9,11, 19
X	EP 1 464 292 A (DEPUY SPINE) 6 October 2004 (2004-10-06)	1,10,12, 13
A	paragraph [0034]	2-9,11, 19

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[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

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"O" document referring to an oral disclosure, use, exhibition or other means

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"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

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"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
20 March 2007	05/06/2007

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Nice, Philip

INTERNATIONAL SEARCH REPORT

International application No
PCT/IB2006/053014

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y A	DE 41 04 092 A (RIEGER C.) 14 August 1991 (1991-08-14) abstract; figures	2-4,6,8, 9,11,19 7
Y A	WO 96/19940 A (OMRIX BIOPHARMACEUTICALS) 4 July 1996 (1996-07-04) page 8, line 10 - page 9, line 24; figures 3-6	5,7 2,6
A	WO 2004/075965 A (SCIMED LIFE SYSTEMS) 10 September 2004 (2004-09-10) claim 5; figures 1,2,8-15,17,18	2-4,6,19
A	US 2004/054377 A1 (FOSTER T.L. & ROEMER F.D.) 18 March 2004 (2004-03-18) cited in the application	
A	US 5 514 137 A (COUTTS R.D.) 7 May 1996 (1996-05-07) column 17, line 18 - line 57; figures 11,12	
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INTERNATIONAL SEARCH REPORT

International application No.
PCT/IB2006/053014

Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 20-21
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [X] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

see annex

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-13,19

Deformable cannula, with a series of joints or a sleeve or sealing layer

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2. claims: 14-18

Cannula with multiple inlet ports

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/IB2006/053014

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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